JONES DAY

COMMENTARY

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False Claims Act's "Rigorous" Materiality Standard Enforced by Second Circuit

IN SHORT

The Situation: A decision by the U.S. Court of Appeals for the Second Circuit reinforces the growing body of case law regarding the strict materiality requirements of the False Claims Act.

The Result: *Coyne v. Amgen* is evidence of the impact the Supreme Court's decision in *Universal Health Services, Inc. v. Escobar* has had on the FCA's materiality standards.

Looking Ahead: Applying *Escobar*'s "rigorous" standard on a motion to dismiss, *Coyne* shows that materiality must be alleged with some detail in FCA cases.

The U.S. Court of Appeals for the Second Circuit, in a recent decision in *Coyne v. Amgen, Inc.*, 17-1522-cv, added to the growing body of case law enforcing the False Claims Act's ("FCA") materiality requirement strictly after the Supreme Court's landmark decision in *Universal Health Services, Inc. v. Escobar*, 136 S. Ct. 1989 (2016). Reviewing the district court's grant of a motion to dismiss under the FCA's public disclosure bar, the Second Circuit instead affirmed on alternative grounds, under *Escobar*'s materiality standard. Though a nonprecedential ruling, *Coyne* shows the enormous impact that *Escobar* has had on FCA litigation—and, in particular, how courts are following the Supreme Court's guidance to enforce materiality strictly even on the pleadings, as happened in *Coyne*.

Coyne concerned the drug Epogen, manufactured by defendant Amgen, Inc. ("Amgen") and approved by the Food and Drug Administration ("FDA") to treat anemia in patients with chronic kidney disease. Relator Dr. Daniel Coyne—a former paid speaker for Amgen—alleged that Epogen's packaging was misleading. Specifically, he alleged that Epogen's packaging set forth the drug's FDA-approved usage to treat chronic kidney disease by raising hemoglobin levels to a target of 10-12 grams per deciliter (g/dL) but did not suggest any differences within that range, even though Amgen knew that taking Epogen beyond the 11 g/dL level would not confer any discernable quality of life benefits. Coyne alleged that Amgen learned this from a clinical trial of patients who maintained hemoglobin levels of 9-11 g/dL ("low arm") and 13-15 g/dL ("high arm"); in 1996, after patients in the study's high arm experienced an increase in adverse events, Amgen halted the study and reported the results to the FDA. Coyne alleged that Amgen continued to market Epogen as approved for usage up to 12 g/dL without noting the drug's limitations in the label.

> *Coyne* is the latest evidence that courts are taking seriously the Supreme Court's statements in *Escobar* that the FCA's materiality requirement is 'rigorous.'

According to Coyne's complaint, between 1996 and 2011, Amgen's purportedly misleading packaging for Epogen caused the submission of false claims to the Centers for Medicare and Medicaid Services ("CMS") that implicitly certified compliance with CMS's requirement that prescribed medication be "reasonable and necessary" under 42 U.S.C. § 1395y(a)(1)(A). After the district court granted Amgen's motion to dismiss on public-disclosure grounds, Coyne appealed.

Instead of addressing the public-disclosure arguments, the Second Circuit affirmed on alternate grounds of materiality. Emphasizing that "the complaint must present *concrete allegations* from which the court may draw the reasonable inference that the misrepresentations on Epogen's packaging and marketing materials *caused the Government to make the reimbursement decision*," the court explained that Coyne's complaint merely "relies on a conclusory assertion that Amgen's failure to disclose the [above] study to CMS was material to, or in effect caused, payment" (emphasis added). This was not enough.

Moreover, the court found that the concrete facts only belied Coyne's claim: because the 10-12 g/dL range was FDA-approved, prescriptions consistent with that use were "presumptively 'reasonable and necessary' for purposes of CMS reimbursement." In addition, the court pointed to new labeling for Epogen in 2007—which was not cited in the complaint, but was publicly available—that added the very information that Coyne contended had been previously missing. The court concluded that, "armed with this information, CMS did not alter its reimbursement practices with respect to Epogen or exercise any independent discretion from the presumption of FDA approval." The government's practices thus showed that "any concealment of the [study's] data from CMS was immaterial to its payment decisions."

Coyne is the latest evidence that courts are taking seriously the Supreme Court's statements in *Escobar* that the FCA's materiality requirement is "rigorous," that it is not "sufficient for a finding of materiality

that the Government would have the option to decline to pay if it knew of the defendant's noncompliance," and that this standard is not too fact-sensitive to be enforced on a motion to dismiss. Indeed, *Coyne* demonstrates that courts will consider publicly available materials outside the record—even on a motion to dismiss—when evaluating materiality. Applying *Escobar*'s "rigorous" standard, *Coyne* shows that materiality must be alleged with some detail and bolsters the growing consensus that the government's decision to continue paying claims with knowledge of the misrepresentation precludes a finding of materiality.

TWO KEY TAKEAWAYS

1. The *Coyne* decision is further illustration that courts are taking seriously the Supreme Court's statements in *Escobar* that the FCA's materiality requirement is "rigorous."
2. *Coyne* also demonstrates that courts will consider publicly available materials outside the record when evaluating materiality.

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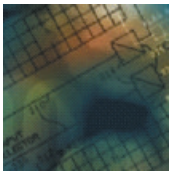

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